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10/664,454

09/17/2003

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

07/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/664,454 | <b>Applicant(s)</b><br>JENSON, MARK L. |  |
|                              | <b>Examiner</b><br>ANN SCHILLINGER   | <b>Art Unit</b><br>3774                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15, 27, 48, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. (US Pat. No. 6,149,681). Houser et al. discloses the following of the claimed invention as shown in Figure 42: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (inner element 246); a second polymeric liner (outer element 246); an intermediate structural member or elongate stent (258) interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments and openings therebetween such that the first liner is bonded to the second liner through said openings to form at least one pocket adjacent to said solid segments, said pocket being defined by said first and second liners and said solid segments; and a fluid containing a bioactive agent disposed within said pocket adjacent to said solid segments of said intermediate structural member (col. 3, lines 41-52). Houser et al. further discloses the limitations of claims 13-15 in col. 7, lines 50-58.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rudakov et al. (US Pat. No. 6,451,050). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not disclose encapsulating a bioactive agent in a polymeric matrix. Rudakov et al. teaches a stent where the bioactive agent is encapsulated in a polymeric matrix in col. 4, lines 40-50 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rudakov et al., as shown in claim 11, further in view of Helmus et al. (US Pub. No. 2002/0032477). Houser et al., as modified by Rudakov et al., discloses the invention substantially as claimed, however, they do not disclose constructing the polymeric matrix holding the bioactive agent of microparticles. Helmus et al. teaches a biological prosthesis that uses microparticles in the matrix in paragraph 0048 for the purpose of controlling the release of the bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use microparticles in the matrix in order to controlling the release of the bioactive agents.

Claims 16 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Golds et al. (US Pat. No. 6,001,125). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not disclose using porous ePTFE to construct the device. Golds et al. teaches a vascular graft constructed from porous ePTFE in

columns 3 and 4 for the purpose of utilizing the material's enhanced radial strength of the less porous area and the enhanced cell endothelialization associated with the more porous area.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use porous ePTFE in order to utilize the material's radial strength and cell endothelialization.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Buirge et al. (US Pat. No. 5,693,085). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not disclose using a natural polymer to construct the device. Buirge et al. teaches a biological prosthesis that uses a natural polymer to construct the device in col. 6, lines 10-28 for the purpose of providing biological protection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a natural polymer to construct the device in order to provide biological protection.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Yan (US Pat. No. 6,240,616). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not disclose using a bioabsorbable polymer to construct the device. Yan teaches a biological prosthesis that uses a bioabsorbable polymer to construct the device in col. 9, lines 22-36 for the purpose of delivering therapeutic agents to a damaged site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a bioabsorbable polymer to construct the device in order to deliver therapeutic agents to a damaged site in a patient.

Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Rhodes (US Pat. No. 5,665,117). Houser et al. discloses the invention

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substantially as claimed, however, Houser et al. does not disclose using stainless steel or tantalum to construct the device. Rhodes teaches a biological prosthesis that uses stainless steel or tantalum to construct the device in col. 6, lines 8-30 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use stainless steel or tantalum to construct the device in order to utilize the material's biocompatibility.

Claim 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in view of Yang (US Pub. No. 2002/0062147). Houser et al. discloses the invention substantially as claimed, however, Houser et al. does not disclose using a gel to contain the bioactive agent. Yang teaches a biological prosthesis that uses a gel to contain the biological agent in paragraph 0073 for the purpose of retaining the drug in the device for a longer period of time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a gel to contain the bioactive agent in order to retain the drug in the device for a longer period of time.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-27 and 48-51 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Schillinger/  
Examiner, Art Unit 3774

/DAVID J ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774